REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 40-57 and 59-69 are in the application. Of these, claims 47-50, 52 and 62-68 have been withdrawn from consideration as directed to non-elected subject matter.

Amendments to the Specification

The specification has been amended to include a Brief Description of the Drawings based upon the information contained in the drawings themselves and also to include topical headings, where appropriate. These amendments are believed to be fully responsive to the examiner's comments on pages 2-3 of the Official Action.

Amendments to the Claims

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and in many instances to adopt the suggestions kindly made by the examiner. As an example, claim 41 has been amended as suggested to attend to an antecedent basis question. The dependency of claim 44 has been changed to claim 43 for the same reason, namely that fat soluble components find antecedent basis in claim 43.

The "preferably ..." possibilities for claims 54-57 have been revised and adjusted in a manner following the examiner's suggestion for revising claim 54; *see* the last sentence of the partial paragraph on that page.

The spelling in claim 55 has been revised to use American English.

Claim 58 has been deleted in order to advance examination.

It is submitted that all of the pending claims are compliant with 35 USC §112, second paragraph. Favorable consideration is requested.

The balance of the Official Action relates to prior art-based rejections.

Response to Anticipation Rejection

The Examiner argues that the claims lack novelty over Jacobsen (US 5,922,560). The applicant concedes that Jacobsen discloses a composition in which astaxanthin, a vitamin (in the form of an antioxidant), an oil and an emulsifier are present and concedes that there is arguably water present in the yeast extract containing the astaxanthin. The Examiner assumes that if all

these components are present then there is by definition an emulsion formed but in reality this cannot and is not the case.

In Jacobsen, the astaxanthin is present in the yeast cell *Phaffia Rhodozyma*. Astaxanthin actually occurs within the cell wall of this microorganism. A yeast cell has a diameter measured in micrometers (around 3-5 μm). It is a very large cellular structure and is far too big to emulsify. An emulsion is a mixture of two immiscible substances. One substance (the dispersed phase) is dispersed in the other (the continuous phase). An emulsion is therefore homogeneous and exists therefore in a single phase. An emulsion is not a suspension. The material of Jacobsen can never be in a single phase and hence can never be an emulsion as the relatively massive yeast cells containing the astaxanthin cannot form micelles or liposomes. The Jacobsen material will therefore exist as a suspension not an emulsion. Note at no point in Jacobsen is there a statement that an emulsion forms. That is because an emulsion cannot form.

The only way to form an emulsion containing astaxanthin is to isolate the astaxanthin from the yeast before emulsification (or use any other isolated or synthetic source of astaxanthin). That is what is carried out in the present invention. The result is that micelles can be formed which have particle sizes measured in nanometers and hence a proper homogenenous emulsion can be formed.

It is noted that in column 9 of Jacobsen, the author suggests that addition of the emulsifier, oil and antioxidant can take place after drying. If the intention was to form an emulsion then what would be the point of adding an emulsifier to a composition which has only an oil phase? This suggests that the emulsifier is not added to form an emulsion.

The whole point of the instant patent application is actually to overcome the problems of astaxanthin bioavailability. Where the astaxanthin is still in the cell wall of a yeast, it is very poorly bioavailable. Unless the cell wall of the yeast organism is mechanically destroyed or chemically destroyed, the astaxanthin is simply not accessible to a fish or other marine organism.

One of the major benefits of using an emulsion of isolated (or synthetic) astaxanthin is that the small liposomes/micelles formed can integrate with the fat in the marine organism's diet and can therefore become very bioavailable. The inventor has found that at 4 or 5 ppm concentrations, his emulsion is much more bioavailable than a product based on a whole cell organism containing ten times that amount of astaxanthin. The reason is believed to be that the

whole cell yeast is simply to large to integrate into the fat of the marine organisms diet. It is consumed only, perhaps, as a sprayed on additive to pellets and eaten therefore as a whole cell organism. This does not make astaxanthin bioavailable as it is wrapped up in the cell wall.

Many fish feeds are based on microorganisms that might absorb astaxanthin as opposed to eat it. Again, the use of a whole cell yeast containing the astaxanthin makes it impossible for any of that astaxanthin to be absorbed by a microorganism in a marine feed. The particle size is simply to big for absorption. In contrast, the emulsion of the present invention is homogeneous (its an emulsion) and can be absorbed by microorganisms as the particle sizes are so small. Again, this shows that the bioavailability of the present emulsion is infinitely better than a whole cell product.

In fact, whole cell astaxanthin products are no longer sold in the industry as their bioavailability is so poor. In a study carried out in an aquarium in Dubai, a product based on a whole cell organism (Haematoccocus rather than Phaffia but the particle size is the same) where found to give no benefit to the fish. The fish lost color. When this whole cell product was replaced by the composition of the present invention, the fish regained normal color in 2 weeks.

The applicant knows therefore that the composition described in Jacobsen is not and cannot be an emulsion. The Examiner simply has to consider how a whole cell could be emulsified to see that it cannot happen. Whole cells do not dissolve either in oil or water - you cannot emulsify them. At best you might be able to suspend them but suspensions eventual settle out and are not emulsions.

The Examiner argues that the Jacobsen disclosure encompasses micelles as these are regarded as forming spontaneously. Micelles cannot form around a whole yeast cell. A typical micelle in aqueous solution forms an aggregate with the hydrophilic "head" regions in contact with surrounding solvent, sequestering the hydrophobic tail regions in the micelle center. Considering the relative size of the cell and the surfactant molecules it is obvious that a micelle cannot form around something so massive. Micelles normally form around bulky molecules such as vitamins but not whole cells. It is submitted therefore that the claims are new.

Response to "Obviousness" Rejections

This invention essentially concerns a food product for marine animals, in particular fish. It is very difficult to ensure that fish outside of their natural environment get all the nutrients they

need to flourish. As noted in the present application and by Jacobsen, astaxanthin has been found to be a critical part of the diet of these organisms and the skilled person has to devise ways of getting the astaxanthin to the fish in sufficiently high dosages.

The present invention is primarily about increasing the bioavailability of astaxanthin over a composition such as that of Jacobsen. Jacobsen attempts to improve bioavailability by increasing the astaxanthin content in a yeast to incredibly high levels. What Jacobsen does not realize is that the problem of bioavailability is associated with the form of the astaxanthin, i.e. the fact that it is present in the cell wall of a whole cell organism, rather than the concentration thereof. The amount of astaxanthin naturally in yeast would have a useful effect on a marine organism if it could actually be given to the organism in an accessible form. The present invention therefore solves the problem of bioavailability by providing the astaxanthin in the form of an emulsion. This is a completely different solution from Jacobsen who attempts to solve the problem by providing whole cell organisms with so much astaxanthin that a bio effective dose can be extracted by the marine organism.

The present solution has numerous benefits. Firstly, it allows the amount of astaxanthin to be altered to any desired level. Different marine organisms need different levels of astaxanthin. With applicant's emulsion, the amounts can be varied precisely by adding more or less of the active material. That is not an option when one uses a whole cell yeast. When using a whole cell, the astaxanthin concentration is what is naturally in the cell.

Moreover, the amounts of astaxanthin used can be much lower when it is provided in the highly bioavailable emulsion form as this oily composition is able to integrate into the fatty parts of fish feed and is therefore readily available to the marine organism when the feed is eaten.

As is clear from the examples of the present invention high levels of astaxanthin in the fish feed are achieved using the composition of the invention. In Example 1, the astaxanthin content is 0.05% (lucantin pink is synthetic astaxanthin) in the feed product, i.e. around 500 ppm. This is then diluted a 4kg/400L, so by 100 times. The total astaxanthin content of the feed of the invention is around 5 ppm. Our results show a significant increase in astaxanthin content in the shrimp feeds in the examples. Note that the whole yeasts of Jacobsen have at least 3000 ppm of astaxanthin!

As noted above, applicant's emulsion can be absorbed by microorganisms as well as eaten by shrimp and the like. No whole cell product can be absorbed.

The present invention therefore offers a completely different solution to the problems of astaxanthin bioavailability than is offered by Jacobsen. Jacobsen does not teach emulsions and whole cells cannot be emulsified. Whole cells suspensions sediment and do not emulsify. In no way therefore does Jacobsen appreciate that astaxanthin bioavailability can be hugely improved if you take it out of the cell and emulsify it.

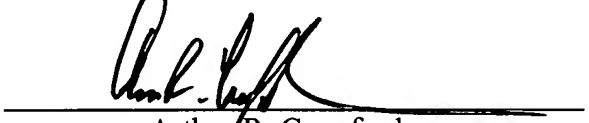
The Examiner considers the combination of Jacobsen and Yokoyama (JP408269079) as this document describes the use of a glucoside of astaxanthin as a color improver for fish. Yokoyama is not relevant to the claims as no emulsion is described therein.

Also included in the Official Action are rejections based on the secondary (or tertiary) references Wein, Burkwall and Dartey. Applicants do not intend to rely on the nature of the emulsifier, stabilizing agent or preservative as affording patentability to the claims thus the above comments serve to distinguish the rejections that include these subsidiary references based on the distinctions with the primary reference or references.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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